

WHAT IS CLAIMED IS:

1           1. A combined radiation and radiosensitizer delivery catheter for  
2 inhibiting hyperplasia, comprising:  
3           a catheter body having a proximal end and a distal end;  
4           an ionizing radiation source coupleable to the catheter body for applying a  
5 radiation dose to a body lumen; and  
6           means coupleable to the catheter body or the radiation source for releasing a  
7 radiosensitizer to the body lumen.

1           2. A delivery catheter as in claim 1, wherein the ionizing radiation source  
2 is an x-ray tube.

1           3. A delivery catheter as in claim 1, wherein the ionizing radiation source  
2 is a radioisotope.

1           4. A delivery catheter as in claim 1, wherein the ionizing radiation source  
2 is a receptacle in the catheter body for receiving radioisotopic materials.

1           5. A delivery catheter as in claim 1, wherein the means comprises a  
2 source of at least one radiosensitizer selected from the group consisting of taxol,  
3 misonidazole, metronidazole, etanidazole, 5-fluorouracil, texaphyrin, C225, and  
4 cyclooxygenase-2 inhibitor.

1           6. A delivery catheter as in claim 1, wherein the means comprises a  
2 source of taxol incorporated in a solution with polyoxyethylated castor oil and dehydrated  
3 alcohol.

1           7. A delivery catheter as in claim 1, wherein the radiosensitizer is  
2 attached or encapsulated in a lipid or surfactant carrier.

1           8. A delivery catheter as in claim 1, wherein the means for releasing the  
2 radiosensitizer comprises a microporous balloon on the catheter body.

1           9. A delivery catheter as in claim 8, wherein the microporous balloon  
2 contains the radiosensitizer and the radiosensitizer is released from the microporous balloon  
3 by elution from pores.

1                   10. A delivery catheter as in claim 9, wherein the microporous balloon is  
2 inflatable with the radiosensitizer.

1                   11. A delivery catheter as in claim 1, wherein the means for releasing the  
2 radiosensitizer comprises a matrix formed over at least a portion of a balloon on the catheter  
3 body, wherein the radiosensitizer is in or beneath the matrix.

1                   12. A delivery catheter as in claim 11, wherein the matrix comprises a rate  
2 controlling material, wherein the rate controlling material controls the rate at which the  
3 radiosensitizer is released from or through the matrix.

1                   13. A delivery catheter as in claim 12, wherein the radiosensitizer is  
2 released from the matrix by diffusion through the matrix.

1                   14. A delivery catheter as in claim 12, wherein the radiosensitizer is  
2 released from the matrix by degradation of the matrix.

1                   15. A delivery catheter as in claim 12, wherein the rate controlling material  
2 is porous and the radiosensitizer is released from the material by elution from pores.

1                   16. A delivery catheter as in claim 11, wherein the radiosensitizer is  
2 disposed on the balloon.

1                   17. A delivery catheter as in claim 8 or 11, wherein the ionizing radiation  
2 source is positionable within the balloon.

1                   18. A delivery catheter as in claim 1, wherein the ionizing radiation source  
2 is a radioisotopic balloon and the means for releasing the radiosensitizer comprises a matrix  
3 formed over at least a portion of the radioisotopic balloon, wherein the radiosensitizer is in or  
4 beneath the matrix.

1                   19. A delivery catheter as in claim 8, 11, or 18, further comprising  
2 perfusion threading on an outer surface of the balloon.

1                   20. A delivery catheter as in claim 19, wherein the threading has a spiral,  
2 helical, or angled pattern.

21. A delivery catheter as in claim 8, 11, or 18, wherein the catheter body has a perfusion lumen.

20. A combined radiation and radiosensitizer delivery catheter for inhibiting hyperplasia, comprising:

a catheter body having a proximal end, a distal end, and an infusion lumen for releasing a radiosensitizer;

a pair of axially spaced apart balloons on the catheter body; and

an ionizing radiation source coupleable to the catheter body for applying a radiation dose between the axially spaced apart balloons.

23. A delivery catheter as in claim 22, further comprising a source for releasing at least one radiosensitizer selected from the group consisting of taxol, misonidazole, metronidazole, etanidazole, 5-fluorouracil, texaphyrin, C225, and cyclooxygenase-2 inhibitor.

24. A method for inhibiting hyperplasia in a body lumen, said method comprising:  
releasing a radiosensitizer at a target region within the body lumen; and  
directing ionizing radiation at the target region, wherein the radiosensitizer and radiation combine to inhibit hyperplasia.

25. A method as in claim 24, further comprising inflating a balloon at the target region, where the radiosensitizer is released from the balloon.

26. A method as in claim 25, wherein the balloon is inflated with the radiosensitizer and the radiosensitizer is released from an interior of the balloon through pores.

27. A method as in claim 25, wherein the radiosensitizer is released from a surface of the balloon.

28. A method as in claim 27, wherein the radiosensitizer is released through a rate controlling matrix.

1                   29.    A method as in claim 24, further comprising isolating the target region,  
2   wherein the radiosensitizer is released into the isolated region.

1                   30.    A method as in claim 29, wherein isolating comprises inflating a pair  
2   of axially spaced apart balloons.

1                   31.    A method as in claim 29, wherein isolating comprises expanding a pair  
2   of axially spaced apart mechanical barriers.

1                   32.    A method as in claim 25, wherein the directing comprises positioning  
2   an ionizing radiation source within the balloon.

1                   33.    A method as in claim 29, wherein the directing comprises positioning  
2   an ionizing radiation source within the isolated target region.

1                   34.    A method as in claim 32 or 33, wherein the ionizing radiation source is  
2   an x-ray tube and positioning comprises energizing the x-ray tube and translating the x-ray  
3   tube to traverse the target region.

1                   35.    A method as in claim 32 or 33, wherein the ionizing radiation source is  
2   a radioisotope.

1                   36.    A method as in claim 32 or 33, wherein the ionizing radiation source is  
2   a receptacle in the catheter body and positioning comprises introducing a radioisotope into  
3   the receptacle.

1                   37.    A method as in claim 24, wherein the body lumen is a blood vessel and  
2   the target region is a region at risk of hyperplasia.

1                   38.    A method as in claim 24, wherein the directing comprises applying a  
2   total radiation dose in a range from about 4 Gy to 24 Gy.

1                   39.    A method as in claim 24, wherein the releasing a radiosensitizer and  
2   directing an ionizing radiation dose are carried out simultaneously.

1                   40.    A method as in claim 24, wherein the releasing a radiosensitizer and  
2   directing an ionizing radiation dose are carried out sequentially.

1           41.    A kit comprising:  
2            a catheter capable of applying a radiation dose and releasing a radiosensitizer  
3            in a body lumen; and  
4            instructions to use the catheter according to any one of claims 24-40.

1           42.    A kit as in claim 41, further comprising a source of radiosensitizer.